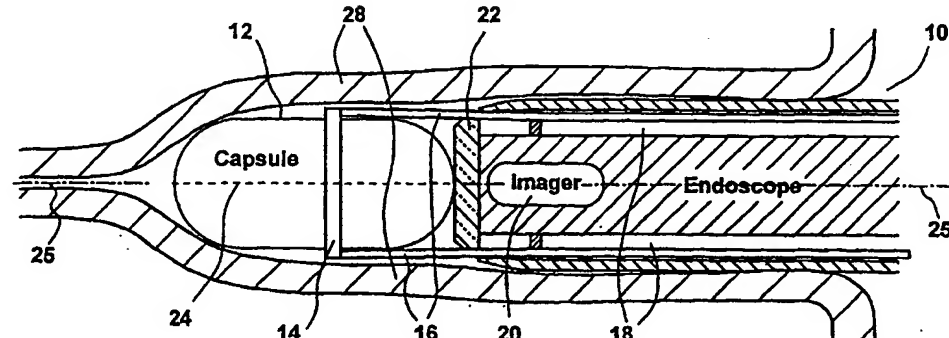




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/IL98/00621 (22) International Filing Date: 22 December 1998 (22.12.98) (30) Priority Data: 122716 22 December 1997 (22.12.97) IL (71) Applicant (for all designated States except US): GIVEN IMAGING LTD. [IL/IL]; Building 7B, 20692 Yokneam Ilite (IL). (72) Inventors; and (75) Inventors/Applicants (for US only): GAVRIEL, J., Iddan [IL/IL]; Einstein Street 44A, 34602 Haifa (IL). GAVRIEL, Meron [IL/IL]; Weizmann Street 21B, 49556 Petach Tikva (IL). (74) Agent: EITAN, PEARL, LATZER & COHEN-ZEDEK; Gav Yam Center 2, Shenkar Street 7, 46725 Herzlia (IL).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>Without international search report and to be republished upon receipt of that report.</i>
(54) Title: SYSTEM AND METHOD FOR IN VIVO DELIVERY OF AUTONOMOUS CAPSULE  (57) Abstract <p>A device for delivering autonomous capsules into the G.I. tract is provided. The device includes an endoscope having a longitudinal axis and a clamp for releasably holding the capsule whereby the longitudinal axis of the capsule lies along the same axis as the longitudinal axis of the endoscope. The clamp is held in the front of the endoscope by at least one support. A forward looking imaging unit is also situated at the front end of the endoscope.</p>		

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SYSTEM AND METHOD FOR IN VIVO DELIVERY OF AUTONOMOUS CAPSULE

FIELD OF THE INVENTION

The present invention concerns a delivery system for autonomous
5 capsules used in internal imaging of the gastro-intestinal tract.

BACKGROUND OF THE INVENTION

Endoscopic inspection is a common practice in the medical diagnosis of
gastro-intestinal (G.I.) diseases. According to such a method, the video camera
used for identifying observable irregularities of the internal lining of the G.I. tract is
10 installed within an endoscope, with progressive scenes observed by pushing the
endoscope inside the tract. The endoscope is a tubular device typically containing
an image collecting device, a light source and optionally a remotely controlled
mechanical appliance for sampling tissue and for manipulating the endoscope tip.
A device such as the tissue sampler, which is a claw- like utility for picking out
15 tissue parts for purposes such as biopsies, is generally manipulated by a cable or
a rod. For that purpose, endoscopes often comprises a bore for housing such
longitudinal mechanical power drivers.

Because the movement of the endoscope head along the G.I. tract is
brought about by a pushing action, there are affects associated with the application
20 of force which become especially adverse as bends in the G.I. tract impede the
movement of the endoscope. The G.I. tract walls at the bends become
susceptible to perforation, making the internal *in vivo* application of probes, notably
endoscopes, limited in use to non-convoluted regions of the G.I. tract.

An *in-vivo* autonomous capsule, such as the one described in US Patent 5,604,531, moves along the G.I. tract by virtue of the natural squeezing action of the tract's walls, thus overcoming the risk associated with the pushing. Another advantage arising from the employment of such an autonomous device, is that it
5 offers a much more convenient method of administering a sensor to the G.I. tract, overcoming the cumbersome aspects of connecting the intestines of the patient to external appliances. Thus, data signals, typically electronic, of the gastro-intestinal tract are obtained without physical connections being made to an energy source or a physical information download link. Autonomous capsules are potentially
10 convenient and useful tools for acquiring information of the inner lining of the G.I. tract, being especially beneficial for searching the small intestines which are highly convoluted. Other autonomous capsule types are used in medicine, such as pH measuring, motility measuring, pressure measuring, and those used for internal administration of medicaments.

SUMMARY OF THE PRESENT INVENTION

It is an object of the present invention to provide a device and method for inserting an autonomous capsule in the G.I. tract, in a manner that the capsule begins its autonomous journey in the small intestines, while obviating the need to travel along the upper part of the G.I. tract.

In accordance with a preferred embodiment of the invention, a device is provided for delivering autonomous capsules into the G.I. tract. Such a device includes an endoscope having a longitudinal axis and a clamp for releasably holding the capsule whereby its longitudinal axis lies along the same axis as the longitudinal axis of the endoscope. The clamp is held in the front of the endoscope by at least one support. A forward looking imaging unit is also situated at the front end of the endoscope,

In accordance with a preferred embodiment of the invention, the clamp is ring shaped such that its inner radius holds the capsule tightly.

In an alternative embodiment, the clamp is a tissue sampler.

Additionally, in accordance with a preferred embodiment of the invention, there is provided a method for inserting an autonomous capsule into the G.I. tract using an endoscope. The endoscope has a clamp and at least one retractable support for retaining the clamp. The method includes the steps of:

engaging the capsule with the clamp;
pushing the capsule to its desired position within the G.I. tract; and
disengaging the capsule by loosening the hold of the clamp on the capsule.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the appended drawings in which:

5 Fig. 1 is a schematic illustration of a delivery system for inserting autonomous capsules for data collecting, in the G.I. tract;

 Fig. 2 is a schematic illustration of a delivery system as in Fig. 1 wherein the direction of pulling the clamp supports is shown;

 Fig. 3 is a schematic illustration of a detached capsule with fully retracted
10 supports, and the fields of view of both imaging systems is marked in arrows; and

 Fig. 4 is a schematic illustration of a delivery system for a capsule, wherein the delivery system has a single cable control mechanism.

DETAILED DESCRIPTION OF THE INVENTION

Reference is now made to Fig. 1, which schematically shows a modified endoscope 10 engaging a capsule 12, constructed and operative in accordance with a preferred embodiment of the present invention. The endoscope device 10, shown inserted tightly within the walls of a G.I. tract 28, comprises a ring clamp 14 with retractable supports 16. The endoscope 10 also comprises a camera (imager) 20, for taking images through an optical window 22.

The capsule 12 is attached to the front of the endoscope with its longitudinal axis 24 parallel (and in line with) to the longitudinal axis 25 of the endoscope. The capsule 12, which abuts window 22, is held in place by the ring clamp 14, which is itself supported by the pair of retractable supports 16. Retractable supports 16 are movable within a bore 18, along the entire length of the endoscope 10.

The modified endoscope 10 of the invention can insert an autonomous capsule 12 in a target location within the G.I. tract 28 in a manually controlled fashion, thereby achieving several goals. In particular, endoscope 10 can be used to expeditiously insert the autonomous capsule 12 in a desired location, thus reducing the time required for the autonomous capsule to reach its target. As a result, the autonomous capsule has more time in which to collect data. The modified endoscope can be used in the non-convoluted terminal of the G.I. tract.

Fig. 2 shows the device of Fig. 1 with the ends of the clamp supports 16 shown protruding outside of the patient's body. The arrows 26 indicate the direction of pull needed to bring about the retraction for disengaging the capsule 12. The capsule, being substantially cylindrical, is held snugly by the ring clamp

14. When the clamp's supports 16 are retracted within bore 18, the clamp 14 slides along the smooth surface of the capsule, and eventually loosens its grip on the capsule 12. Thus, the capsule 12 is deposited in position as soon as full retraction of the clamp 14 has taken place. Fig. 2 illustrates the capsule 12 retracted to a stage in which the capsule 12 abuts against the window 22 of the endoscope 10. The window 22 therefore blocks the capsule's further retraction movement, thereby facilitating the sliding of the ring 14 on the capsule's surface. Disengagement of the capsule takes place only as the clamp 14 has slipped by the back end (referenced 32) of the capsule 12, due to the pulling of the supports 16 manually in the direction indicated by arrows 26 away from the capsule 12. This particular situation is shown in Fig. 3, which also shows the capsule 12 detached from the endoscope 10.

An autonomous capsule of an imaging type, such as described in US Patent No: 5,604,531, can be used to verify its own place of insertion in the G.I. tract as it is pushed along. Once it is deposited, it can continue to acquire images autonomously. Fig. 3, shows the viewing range (arrows 27) of the detached capsule 12, as well as the viewing range (arrows 29) of the imager 20 in the endoscope. The endoscope becomes operative as a camera once the capsule 12 has detached.

20 In another embodiment of the invention, a tissue sampler, known for its function as an aid in obtaining pieces of tissue out of the G.I. tract, can be used for holding and delivering an autonomous capsule.

In another embodiment of the invention, a single bore endoscope is shown in Fig. 4 to which reference is now made, the release of the capsule clamp is

implemented by a single, loosely sheathed cable. In this embodiment, the clamp 30 comprises upper and a lower segments, joined together by a pin 38, which are held by supports 34 and 32, respectively. The upper support 34 is soldered to a sheath 40 of a cable 44, and the lower support 32 is connected via a flexibly pivot 5 48 to one end 46 of cable 44. A helical spring 36, inserted between cable sheath 40 and cable end 46, to keep them apart.

In operation, the capsule 12 is held by the effect of the support 32 pushing the lower clamp segment upwards. Spring 36 produces a torque through pin 38, such that force is applied inwards by the segments of clamp 30 holding the 10 capsule 12 tightly.

Release of capsule 12 is brought about by pulling cable 44 which, in turn, causes contraction of spring 36 and the torque applied through pin 38 in the direction that causes the clamp segments 30 to loosen their grip around capsule 12.

15 It will be appreciated that the present invention is not limited by what has been described hereinabove and that numerous modifications, all of which fall within the scope of the present invention, exist. For example, the number of supports of the clamp can be other than described.

It will be appreciated by persons skilled in the art that the present invention 20 is not limited by what has been particularly shown and described herein above. Rather the scope of the invention is defined by the claims which follow:

CLAIMS

1. A device for delivering an autonomous capsule having a first longitudinal axis, into the G.I. tract, the device comprising:
 - an endoscope having a second longitudinal axis;
 - 5 a clamp for releasably holding said capsule; and
 - at least one retractable support for retaining said clamp at the front end of said endoscope, said at least one support being movable within said endoscope.
2. A device according to claim 1 and further comprising an imaging unit
10 situated at the front end of said endoscope.
3. A device according to claim 1 wherein said first longitudinal axis lies on the same axis as said second longitudinal axis.
4. A device according to claim 1 in which said clamp is a tissue sampler.
5. A device according to claim 1 wherein said clamp is ring shaped.
- 15 6. A method for inserting an autonomous capsule into the G.I. tract by an endoscope, said endoscope having a clamp and at least one retractable support for retaining said clamp, the method comprising the steps of:
 - engaging said capsule with said clamp;
 - pushing said capsule to its desired position within the G.I. tract;
 - 20 and
 - disengaging said capsule by loosening the hold of said clamp on said capsule.

7. The method according to claim 6 and further comprising the step of:
verifying the efficacy of said inserting by observing the capsule
through an imaging unit placed within said endoscope.

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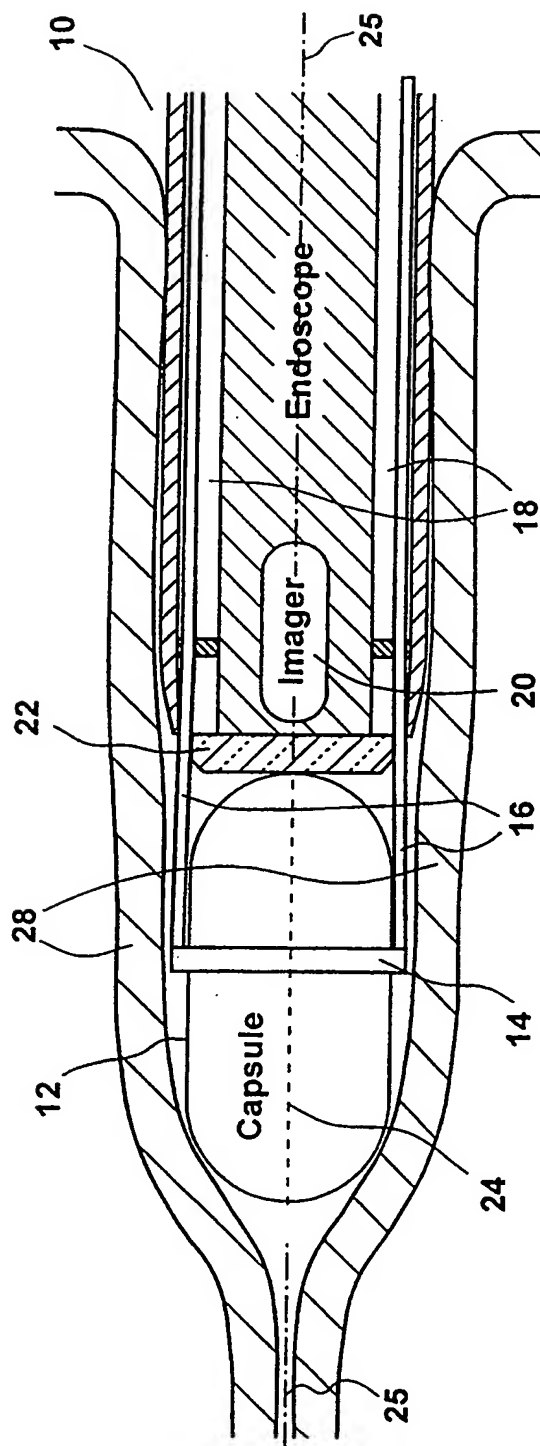


FIG. 1

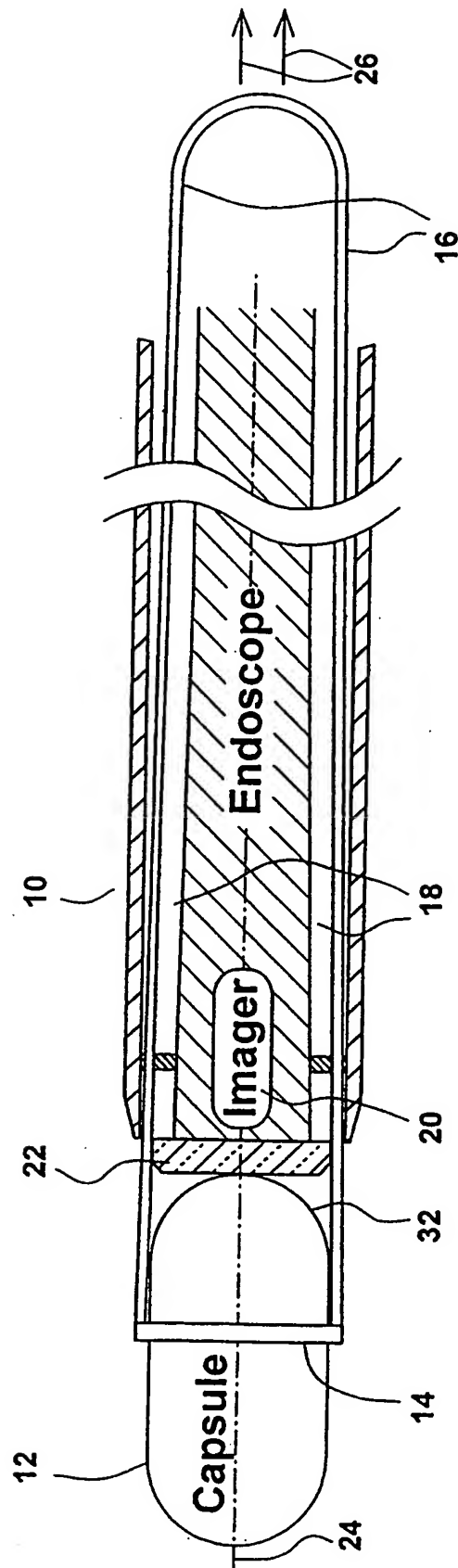


FIG. 2

3/ 4

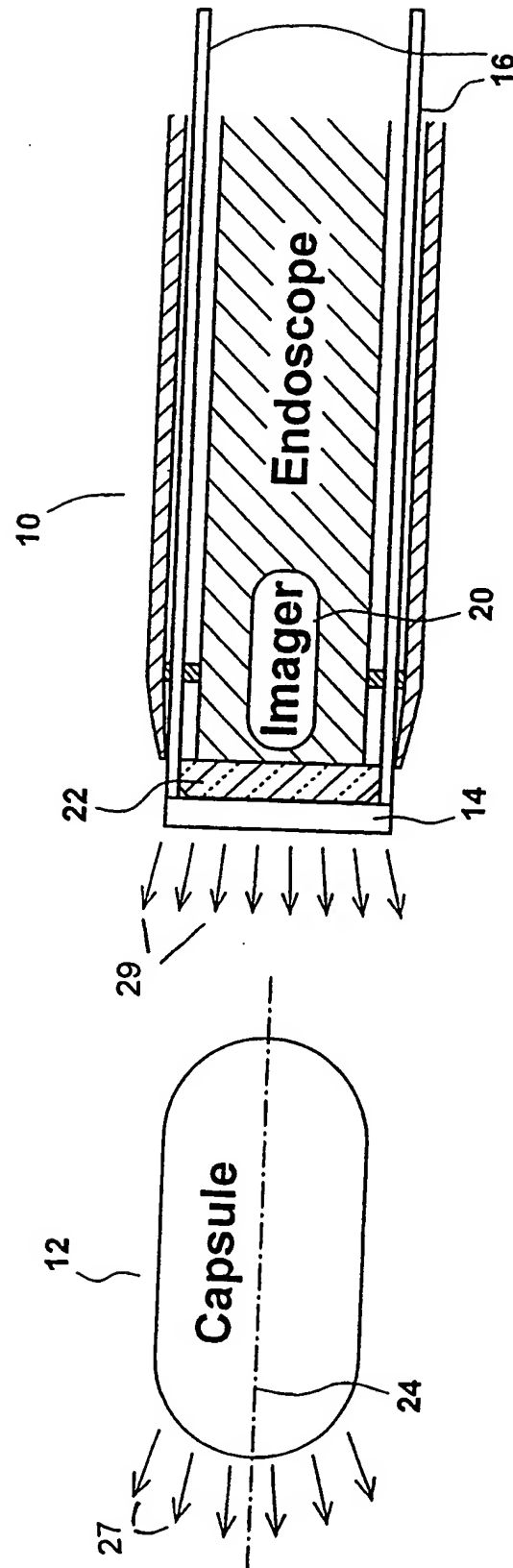


FIG. 3

4/ 4

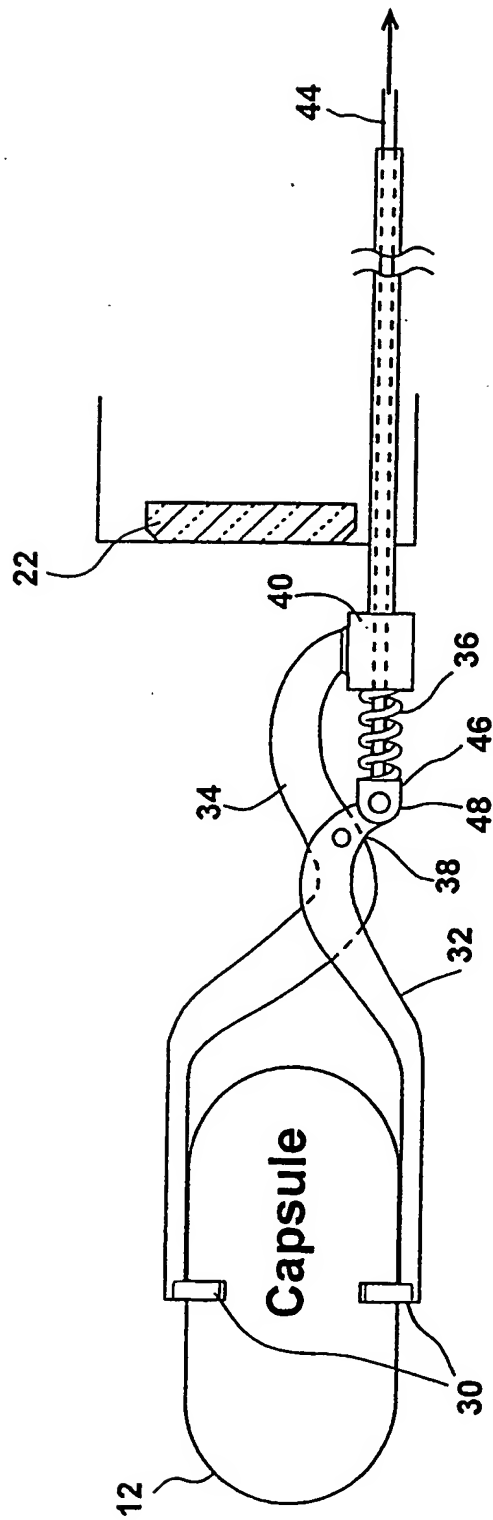
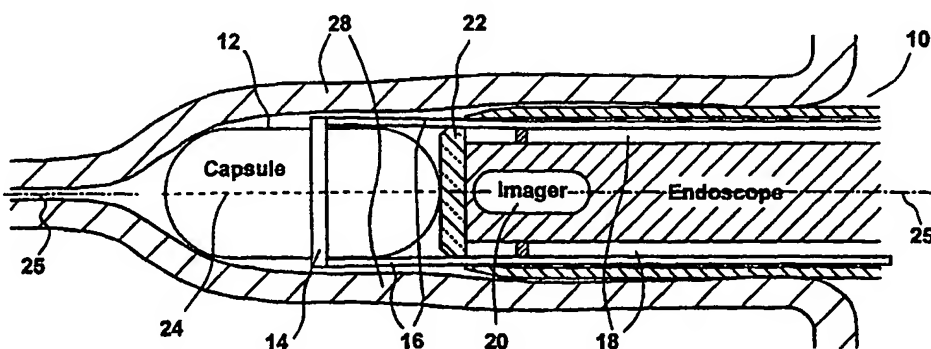


FIG. 4

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/IL98/00621 (22) International Filing Date: 22 December 1998 (22.12.98) (30) Priority Data: 122716 22 December 1997 (22.12.97) IL (71) Applicant (for all designated States except US): GIVEN IMAGING LTD. (IL/IL); Building 7B, 20692 Yokneam Ilite (IL). (72) Inventors; and (75) Inventors/Applicants (for US only): GAVRIEL, J., Iddan [IL/IL]; Einstein Street 44A, 34602 Haifa (IL). GAVRIEL, Meron [IL/IL]; Weizmann Street 21B, 49556 Petach Tikva (IL). (74) Agent: EITAN, PEARL, LATZER & COHEN-ZEDEK; Gav Yam Center 2, Shenkar Street 7, 46725 Herzlia (IL).	(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> (88) Date of publication of the international search report: 10 September 1999 (10.09.99)	
(54) Title: SYSTEM AND METHOD FOR IN VIVO DELIVERY OF AUTONOMOUS CAPSULE  (57) Abstract <p>A device for delivering autonomous capsules into the G.I. tract is provided. The device includes an endoscope (10) having a longitudinal axis (25) and a clamp (14) for releasably holding the capsule (12) whereby the longitudinal axis of the capsule (24) lies along the same axis as the longitudinal axis of the endoscope. The clamp (14) is held in the front of the endoscope by at least one support (16). A forward looking imaging unit (20) is also situated at the front end of the endoscope.</p>		

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL98/00621

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 1/012

US CL :600/104

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/101, 104, 106, 129, 127

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
none

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

search terms: endoscope, fiberscope, capsule, G.I., gastrointestinal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,198,960 A (UTSUGI) 22 April 1980, see Figures 4-7 and col.3, line 21 to col.5, line 33.	1-5
X	US 4,027,510 A (HILTEBRANDT) 07 June 1977, see entire disclosure.	1-4
X	US 5,373,840 A (KNIGHTON) 20 December 1994, see Figures 1-3.	1-5

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

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Date of the actual completion of the international search

15 JUNE 1999

Date of mailing of the international search report

09 JUL 1999

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